

Sterility Testing

The direct inoculation method:

Involves introducing test samples directly into nutrient media.

Two media:

- **Fluid mercaptoacetate medium** : contains glucose and sodium mercaptoacetate and is particularly suitable for the cultivation of anaerobic organisms (**incubation temperature 30 – 35 ° C**)
- **Soyabean casein digest medium**: support the growth of both aerobic bacteria (incubation temperature 30 – 35 ° C) and fungi (**incubation temperature 20 – 25 ° C**).

Membrane filtration:

This method by which the great majority of products are examined

- ❖ It involves filtration of fluids through a sterile membrane filter (pore size $\leq 0.45 \mu m$),
- ❖ Any microorganism present being retained on the surface of the filter.
- ❖ After washing in situ, the filter is divided aseptically and portions are transferred to suitable culture media, which are then **incubated** at the appropriate temperature for the required period of time.
- ❖ Water - soluble solids can be dissolved in a suitable diluent and processed in this way and oil – soluble products may be dissolved in a suitable solvent, e.g. isopropyl myristate.

A sensitive method:

- For detecting low levels of contamination in **intravenous infusion fluids**.
- Involves the addition of **a concentrated culture medium** to the fluid in its original container.
- Such that the resultant mixture is equivalent to **single strength** culture medium.
- In this way, sampling of the entire volume is achieved.-+